

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA,)	
)	
Plaintiff,)	
)	
v.)	Case No. 4:21-cv-1165
)	
OLIVE STREET PHARMACY, LLC, and)	
IRINA SHLAFSHTEYN.)	
)	
Defendants.)	
)	

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its attorney, Sayler A. Fleming, United States Attorney for the Eastern District of Missouri, having brought an action against Olive Street Pharmacy, LLC (Olive Street) and Irina Shlafshiteyn (Shlafshiteyn) (together, Defendants) seeking civil monetary penalties and injunctive relief for violations of the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* (the CSA);

Olive Street having appeared in this action by its attorneys, Steve E. Holtshouser and Christina B. Moore, and Shlafshiteyn having appeared in this action by her attorney, Daniel A. Juengel, and both Olive Street and Shlafshiteyn having waived service of process, and having consented to entry of this Consent Decree without contesting the allegations of the Complaint;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

Jurisdiction and Venue

1. This Court has subject-matter jurisdiction over this action pursuant to 21 U.S.C. §§ 842(c)(1)(A), 843(f)(2), and 882(a), as well as 28 U.S.C. §§ 1345 and 1355.

2. Olive Street consents to this Court's subject-matter and personal jurisdiction over it.

3. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b)(1) and (b)(2) because this is the district in which Olive Street and Shlafshiteyn reside and where a substantial part of the alleged events or omissions giving rise to the claim occurred, and pursuant to 28 U.S.C. § 1395(a) because this is an action for recovery of a pecuniary fine or penalty and this is the venue where the action accrued or Defendants are found.

4. The United States alleges that Defendants have violated the CSA and its implementing regulations by failing to exercise their corresponding responsibility to ensure that the controlled substances they dispensed, helped dispense, or facilitated dispensing were issued for a legitimate medical purpose by a practitioner acting in the usual course of the practitioner's professional practice as required, *see* 21 C.F.R. § 1306.04, and by filling, helping fill, or facilitating the filling of a prescription for a controlled substance outside the usual course of the professional practice of pharmacy as required by 21 C.F.R. § 1306.06.

5. Without answering or admitting these allegations, Olive Street and Shlafshiteyn agree that the United States' Complaint states a claim for which civil monetary penalties may be awarded against them pursuant to 21 U.S.C. § 842(c) and that the Court may order injunctive relief against Olive Street pursuant to 21 U.S.C. §§ 843(f) and 882.

Civil Monetary Penalty

6. Olive Street and Shlafshiteyn are jointly and severally liable for and shall pay to the United States a civil monetary penalty pursuant to the CSA in the amount of \$1,196,997.90 (one million, one hundred ninety-six thousand, nine hundred ninety-seven dollars and ninety cents).

Injunctive Provisions

7. Upon entry of this decree, Olive Street and each and all of its employees, agents, officers, directors who have any role or responsibility for the filling of controlled substance prescriptions is permanently restrained and enjoined under 21 U.S.C. §§ 843(f)(1) and 882, and the inherent equitable authority of this Court, from directly or indirectly dispensing, assisting in the dispensing, or otherwise facilitating the dispensing of any controlled substance as defined in the CSA or its implementing regulations, unless dispensing the prescription is in compliance with 21 U.S.C. § 842, 21 C.F.R. §§ 1306.04, 1306.06, and any of the Missouri statutes and regulations pertaining to the dispensing of controlled substances. Olive Street is further permanently restrained and enjoined under 21 U.S.C. §§ 843(f)(1) and 882, and the inherent equitable authority of this Court, from seeking and/or continuing enrollment in the Transmucosal Immediate Release Fentanyl Risk Evaluation and Mitigation (TIRF REMS) Program.

8. Furthermore, upon entry of this Decree, Shlafshiteyn is permanently restrained and enjoined under 21 U.S.C. §§ 843(f)(1) and 882, and the inherent equitable authority of this Court, from participating in the ownership of or being employed by any institution or establishment where controlled substances are distributed or dispensed within the meaning of the CSA. Shlafshiteyn is further permanently restrained and enjoined under 21 U.S.C. §§ 843(f)(1) and 882, and the inherent equitable authority of this Court, from directly or indirectly dispensing, assisting in the dispensing, or otherwise facilitating the dispensing of any controlled substance as defined in the CSA or its implementing regulations. In the event that Shlafshiteyn violates this Decree, Shlafshiteyn shall pay a penalty of \$15,000.00 (fifteen thousand dollars) to the United States for each instance constituting a violation of the Decree.

Identification, Resolution and Documentation of Red Flags of Abuse or Diversion

9. To fulfill Olive Street's obligations pursuant to paragraph 7, before dispensing or assisting in the dispensing of any controlled substance prescription, Olive Street must for each prescription:

a. review any available data for the patient in question in the Missouri prescription data monitoring program (PDMP) and reasonably determine whether the prescription was issued for a legitimate medical purpose by an individual practitioner acting in the usual course of the practitioner's professional practice based on the information available from the PDMP, the pharmacy's patient record system or patient profile system, other records available to Olive Street, the prescription itself, and other circumstances surrounding the presentation of the prescription;

b. identify any indication that the prescribed controlled substance may not be for a legitimate medical purpose, or may be abused, misused, or otherwise diverted from legitimate uses; such indications include, *but are not limited to* the following:

i. the patient appears to be returning too frequently such that a prescription which should last for a given period of time when used legitimately is being refilled or is being requested to be refilled more frequently than medically indicated or directed or used;

ii. the patient is receiving prescriptions with counteracting physiological effects, such as depressants and stimulants, during the same therapeutic period such that the patient could be taking both medications concurrently;

iii. the patient is receiving prescriptions for opioids and benzodiazepines during the same therapeutic period such that the patient could be taking both medications concurrently;

iv. the patient presents prescriptions written in the names of people other than the patient;

v. the patient has received the same or similar prescriptions from more than one prescriber during the same therapeutic period such that the patient could be taking them together;

vi. a number of people appear simultaneously, or within a short time, all bearing similar prescriptions from the same physician;

vii. people who are not regular patrons or residents of, or otherwise employed within, the community show up with prescriptions from the same physician;

viii. the prescriber writes significantly more prescriptions (or prescriptions for drug amounts in larger quantities) compared to other practitioners in the same specialty in the area;

ix. the patient lives more than 25 miles driving distance from Olive Street and is not employed within 25 miles driving distance of Olive Street;

x. the patient lives more than 25 miles driving distance from the prescriber and is not employed within 25 miles driving distance of the prescriber;
or

xi. the patient presents a prescription that does not, in the usual course of pharmacy practice, treat the condition indicated by a diagnosis code written on

the prescription or provided by the prescriber, the patient, or any other information available to Olive Street;

xii. the patient presents a prescription for any of the following medications or their generic or brand-name equivalents: short-acting oxycodone if the dosage unit being prescribed contains 30 milligrams; short-acting alprazolam, if two-milligram dosage units are being prescribed; any medication containing short-acting hydrocodone, if the strength of the hydrocodone is 10 milligrams per dosage unit; methadone; or Duragesic.

c. document in detail (1) any indications that the prescribed controlled substance may not be for a legitimate medical purpose, or may be abused, misused, or otherwise diverted from legitimate uses, and (2) the steps that Olive Street took to reasonably ensure that the prescription was issued for a legitimate medical purpose by a prescriber in the usual course of that prescriber's practice and that the prescription would not be abused or diverted for illegitimate purposes.

10. On the tenth business day of January, April, July, and October, Olive Street shall submit to the Drug Enforcement Administration (DEA) copies of all documentation called for under subparagraph 'c' of the prior paragraph. At a minimum, this documentation shall include, for each prescription filled despite the presence of indications of abuse, misuse, diversion, or a lack of legitimate medical purpose during the prior three-month period:

a. identification of all indicators of potential abuse, misuse, diversion, or a lack of legitimate medical purpose;

b. a description of the steps that Olive Street took to fulfill its corresponding responsibility pursuant to 21 C.F.R. § 1306.04, including a statement as to whether any PDMP data was reviewed; and

c. all documentation, except for PDMP data, related to Olive Street's determination that the prescription was issued for a legitimate medical purpose by a prescriber in the usual course of that prescriber's practice and would not be abused or diverted despite indications to the contrary. This provision does not waive any party's right to challenge in any future litigation the extent of the responsibility created by 21 C.F.R. Section 1306.04.

11. DEA's silence with regard to either documentation submitted by Olive Street or the absence of documentation shall not be construed as an indication that Olive Street properly filled the prescription in question. Nor shall DEA's silence be regarded as a waiver of any potential action DEA might take under the law or this decree.

Prohibition against Filling Certain Prescriptions

12. Notwithstanding anything else in this Decree, Olive Street shall not dispense, assist in dispensing, or otherwise facilitate dispensing a prescription for a controlled substance if dispensing the prescription would result in the patient receiving:

a. any medication subject to the TIRF REMS Program, including without limitation the following medications and any of their generic or brand-name equivalents: Subsys, Actiq, Fentora, Lazanda, Onsolis, fentanyl citrate, and fentanyl buccal.

b. a daily dosage in excess of 90 milligram morphine equivalents if the prescription is taken as prescribed, whether on its own or in combination with other prescriptions that the patient is receiving, as reflected in Olive Street's records, in any

available PDMP data, or any other information available to Olive Street, unless prescribed to a patient receiving hospice care at the time of dispensation and Olive Street otherwise fulfills its corresponding responsibility pursuant to 21 C.F.R. § 1306.04;

c. a combination of an opioid, a benzodiazepine, and carisoprodol or any of its brand or generic equivalents, unless prescribed to a patient receiving hospice care at the time of dispensation and Olive Street otherwise fulfills its corresponding responsibility pursuant to 21 C.F.R. § 1306.04;

d. a combination of an opioid, a benzodiazepine, and a stimulant, unless prescribed to a patient receiving hospice care at the time of dispensation and Olive Street otherwise fulfills its corresponding responsibility pursuant to 21 C.F.R. § 1306.04;

e. a combination of an opioid and phentermine;

f. a combination of more than one short-acting narcotic painkiller;

g. a combination of more than one long-acting narcotic painkiller;

h. a prescription for buprenorphine without naloxone (such as Subutex) without reliable documentation from the prescriber that the patient is pregnant, a nursing mother, or has had an actual adverse reaction to naloxone;

i. any prescription that appears to have been tampered with or manipulated from the way in which it appears to have been originally written;

j. an early refill for any controlled substance; or

k. any controlled substance paid for with cash despite the fact that the patient has insurance or federal healthcare program benefits available to pay for the patient's prescriptions.

13. Nothing in this Decree shall diminish or abate Olive Street's duty to fully comply with all applicable provisions of the CSA, including by fulfilling Olive Street's corresponding responsibility as required by 21 C.F.R. § 1306.04. The failure of a prescription for a controlled substance to fall within one of the categories in Paragraph 12, above, does not excuse Olive Street from ensuring, prior to dispensing it, that it has fulfilled its corresponding responsibility under 21 C.F.R. § 1306.04. By entering into this agreement and agreeing to this provision, the Parties reserve the right to challenge in any future litigation the extent of the responsibility created by 21 C.F.R. Section 1306.04.

14. If, at any time after entry of this Decree, the DEA determines that Olive Street has failed to comply with any provision of this Decree, DEA may, as and when it deems necessary, notify Olive Street in writing of the noncompliance and order Olive Street to take corrective action, including, but not limited to, ordering Olive Street to immediately cease ordering, distributing, or dispensing controlled substances. This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this Decree or under the law, including additional civil monetary penalties.

15. The following process and procedures apply when the DEA issues an order under the preceding paragraph:

- a. Olive Street will implement the corrective action ordered by DEA without delay;
- b. For any order calling on Olive Street to cease ordering, distributing, or dispensing controlled substances, any and all DEA registrations under which Olive Street has been operating or that Olive Street otherwise maintains shall be deemed to have been

surrendered for cause and Olive Street will permit DEA immediate access to its premises and permit DEA to seize all controlled substances and controlled substance order forms.

16. If Olive Street notifies and provides reasons to DEA that it does not agree with any DEA order under the prior two paragraphs of this Decree, DEA will review Olive Street's notification and reasons and within 30 days thereafter, in writing, affirm, modify or withdraw its order, as DEA deems appropriate. If DEA affirms or modifies its order, it will explain the basis for its decision in writing. This written notification shall constitute final agency action.

a. If DEA affirms or modifies its order, Olive Street may, within 28 calendar days, seek judicial review of the DEA's order in this Court. Olive Street shall continue to diligently implement DEA's order while judicial review is pending unless and until the Court or any higher court reverses, stays, or modifies DEA's order.

b. All decisions conferred upon DEA in this Decree shall be vested in DEA's discretion and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any DEA decision rendered pursuant to this Decree shall be based exclusively on the written record before DEA at the time the decision was made. No discovery shall be taken by any party.

17. If DEA orders Olive Street to cease ordering, distributing, or dispensing controlled substances under this Decree, and that order is not otherwise reversed, then Olive Street and its officers, members, and directors, shall be prohibited from seeking any further DEA registration, and any application for registration or subsequent registration issued shall be deemed null and void.

18. Representatives of DEA shall be permitted, without prior notice and as and when DEA deems necessary, to inspect Olive Street's operations and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the CSA, and all applicable regulations. During such inspections, DEA representatives shall be permitted to have immediate access to Olive Street's places of business including without limitation all buildings, equipment, pharmaceuticals, computer systems, and records, whether printed or digitally stored. Olive Street will facilitate DEA's access to such items, records, or computer systems. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to inspect under the CSA.

19. Within 5 (five) business days after entry of this Decree, Olive Street shall post a copy of this Decree in Olive Street in a location that will make it conspicuous to Olive Street and any individuals with any responsibility for filling or assisting with the filling of prescriptions at Olive Street and shall ensure that the Decree remains posted for as long as the Decree remains in effect. Within 10 (ten) business days after entry of this Decree, Olive Street shall provide to DEA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph.

20. Within 10 (ten) business days after entry of this Decree, Olive Street shall provide a copy of this Decree by personal service, email (with delivery confirmation), or certified mail (return receipt requested) to each and all of its directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons or entities in active concert or participation with any of them (Associated Persons). Within 20 (twenty) business days after entry of this Decree, Olive Street shall provide to DEA an affidavit, from a person with personal

knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who have received a copy of this Decree, and attaching a copy of the executed certified mail return receipts or email delivery confirmation, as applicable.

21. In the event that Olive Street becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Olive Street shall immediately provide a copy of this Decree, by personal service, email (with delivery confirmation), or certified mail (return receipt requested) to such Associated Person(s). Within 10 (ten) business days after Olive Street becomes associated with any additional Associated Person, Olive Street shall provide to DEA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts, or email delivery confirmation, as applicable.

22. Olive Street shall notify DEA in writing at least 35 (thirty-five) calendar days before any change in ownership, name, or character of its business that occurs after entry of this Decree, including any proposed sale, incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, or any other change in the structure or identity of Olive Street or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Olive Street shall provide a copy of this Decree to any prospective purchaser, successor, or assign at least 28 (twenty-eight) calendar days prior to any sale or assignment, and any such prospective purchaser, successor, or assign shall agree as part of the transaction to be added a defendant to this Decree and be bound to the terms in this Decree to the same extent that Olive Street is bound by them. Olive Street shall furnish

DEA with an affidavit of compliance with this paragraph no later than 21 (twenty-one) calendar days prior to such assignment or change in ownership.

23. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Olive Street shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), expert witness fees, travel expenses incurred by attorneys and witnesses, investigational and analytical expenses, administrative and court costs, and any other costs or fees relating to such contempt proceedings.

24. All notifications, correspondence, and communications to DEA required by the terms of this decree shall be prominently marked "Decree Correspondence" and delivered by electronic mail and hard copy to the attention of Group Supervisor Robert A. Churchwell, Drug Enforcement Administration, St. Louis Diversion Group, 317 South 16th Street, St. Louis, Missouri 63103, and, with the exception of documents being sent pursuant to paragraph 10, the United States Attorney for the Eastern District of Missouri, attention Assistant U.S. Attorney Amy E. Sestric, amy.sestric@usdoj.gov, 111 S. 10th Street, 20th Floor, St. Louis, Missouri 63102, and shall reference this civil action by case name and number. All notifications, correspondence and communications to Olive Street from United States of America and/or DEA under this decree, shall be prominently marked "Decree Correspondence" and shall be delivered to Olive Street by electronic mail and hard copy to: (i) Olive Street Pharmacy, LLC, Attn. Alex Shlafshiteyn shlafik@hotmail.com, 10420 Old Olive Street Road, Suite 103, Creve Coeur, Missouri 63141.

Continuing Jurisdiction and Relief from this Decree

25. No sooner than 5 (five) years after entry of this Decree, Olive Street may petition this Court for relief from this Decree. If Olive Street has maintained a state of continuous material compliance with this Decree, the CSA and its implementing regulations, and any Missouri statute

or regulation pertaining to the distribution of controlled substances during the 5 (five) years preceding Olive Street's petition, the United States will not oppose such petition.

26. No sooner than 10 (ten) years after entry of this Decree, Shlafshiteyn may petition this Court for relief from this Decree. If Shlafshiteyn has maintained a state of continuous material compliance with this Decree, during the 10 (ten) years preceding Shlafshiteyn's petition, the United States will not oppose such petition.

27. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED, this ____ day of _____, 2021.

UNITED STATES DISTRICT JUDGE

Entry consented to:

For Olive Street Pharmacy, LLC

ALEX SHLAFSHITEYN
Authorized Representative

Steve E. Holtshouser
Husch Blackwell LLP
190 Carondelet Plaza, Suite 600
St. Louis, Missouri 63105
steve.holtshouser@huschblackwell.com
(314) 345-6269

For the United States of America

SAYLER A. FLEMING
United States Attorney

Amy E. Sestric
Assistant United States Attorney
111 S. 10th Street, 20th Floor
St. Louis, Missouri 63102
amy.sestric@usdoj.gov
(314) 539-7720

Christina B. Moore
Husch Blackwell LLP
190 Carondelet Plaza, Suite 600
St. Louis, Missouri 63105
christina.moore@huschblackwell.com
(314) 345-6224

For Irina Shlafshteyn

Irina Shlafshteyn

Daniel A. Juengel
Frank, Juengel & Radefeld, Attorneys at Law
7710 Carondelet Avenue, Suite 350
St. Louis, Missouri 63105
djuengel@fjrdefense.com
(314) 282-8657